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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

MELLER, MICHAEL V

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 05/06/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/809,021

Applicant(s)

METZNER ET AL.

Examiner

Michael V. Meller

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on 19 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) 18-38 is/are pending in the application.
- 4a) Of the above claim(s) 20-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18, 19 and 35-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Interview Summary (PTO-413) Paper No(s): \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s): \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO 152)

Art Unit: 1654

## DETAILED ACTION

### *Election/Restrictions*

The restriction requirement is maintained for the reasons of record.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 18, 19, 35-38 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition comprising thrombin, benzamidine or p-aminobenzamidine, nacl, cacl, l-histidine, mannitol, na, succinate, na lactate, l-arginine, does not reasonably provide enablement for any and all inhibitors of thrombin, sugars, sugar alcohols, amino acids, etc.. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The specification as filed, is enabled for a composition comprising thrombin,

Art Unit: 1654

lactate, l-arginine, but is not enabled for any and all inhibitors of thrombin, sugars, sugar alcohols, amino acids, etc...

The art of biotechnology is a highly unpredictable art and it would be an undue burden for one of ordinary skill in the art to test any and all inhibitors of thrombin, sugars, sugar alcohols, amino acids, etc..to see if they could perform the disclosed use.

Applicant has only shown in their examples that a composition comprising thrombin, benzamidine or p-aminobenzamidine, nacl or cacl, l-histidine, l-arginine, mannitol, na succinate, or na lactate even works for the disclosed use. With only knowing these specific components it is clear that such broad claims are not enabled by the instant specification when one of ordinary skill in the art is only given the particular components to produce a composition able to perform the disclosed use.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

the invention was patented, described in a printed publication, or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 18 and 35-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Hanada et al.

Applicants argue that the claims recite that the thrombin preparation is suitable for therapeutic purposes and that the use of trialkylphosphates does not anticipate the claims.

The examiner has already addressed the argument concerning the therapeutic use. First this statement is subjective and relative. The thrombin is used for therapeutic use as has been shown on the record. The use of trialkylphosphates is not a problem since applicant also teaches to use virus inactivation, see page 5 of applicant's own specification, see also the examples in the claims with special attention drawn to the use of Planova. How can applicant state that a compound is added to kill viruses and then in their method also kill viruses with a compound/membrane. The fact of the matter is the reference reads on applicant's invention and thus the rejection is maintained.

Claims 18, 35, 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Allary et al. or Lorne et al.

The references each teach that benzamidine and thrombin are together in a composition.

Claim 38 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hanada et al.

Applicant argues the same arguments as have been addressed above.

Claims 18, 19 and 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hanada et al. taken with Brezniak et al. and Altshuler.

Applicant argues the same arguments as have been addressed above.

Claims 18, 19 and 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allary et al. or Lorne et al. taken with Hanada et al., Brezniak et al. and Altshuler.

The teachings of the references are above. Allary and Lorne show that thrombin and benzamidine are well known in the art to be together for making biological glue as applicants also do.

Hanada teaches the other components in the formulation and their use is also for thrombin production. Brezniak and Altshuler are of record.

Claims 18, 19 and 35-38 are rejected under 35 U.S.C. 103(a) as being  
  
Brezniak et al. and Altshuler.

The teachings of the references are above.

Allary and Lorne show that thrombin and benzamidine are well known in the art to be together for making biological glue as applicants also do.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 703-308-4230. The examiner can normally be reached on Monday thru Friday: 9:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 703-306-3220. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Michael V. Meller  
Primary Examiner  
Art Unit 1654